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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,108	09/29/2000	Lynn Joens	M0-4890	2035

31846 7590 09/30/2004

AKZO NOBEL PHARMA PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966

EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/677,108	Applicant(s) JOENS, LYNN	
	Examiner Robert A. Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 27, 28 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 27-28 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7-21-2004 has been entered.

The amendment and response filed on 7-21-2004 are acknowledged. Claims 3-5, 27-28 and 31 have been amended. Claim 29 has been canceled. Claims 3-5, 27-28 and 31 are pending and currently under examination.

New Claim Objections

Claim 27 is objected to because of the following informalities: The abbreviation for the genus of *L. intracellularis* is used without denoting what said abbreviation stands for upon its first recitation. Appropriate correction is required.

Claim 28 contains an obvious grammatical error. The phrase "is lysate" should read "is a lysate".

Claim Rejections Withdrawn

The rejection of claim 28 under 35 U.S.C. 112, second paragraph, for having insufficient antecedent basis for the limitation "*L. intracellularis* antigen" in line 3 is withdrawn in light of the amendment thereto.

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The rejection of claim 29 under 35 U.S.C. 112, second paragraph, for having insufficient antecedent basis for the limitation "*L. intracellularis* antigen" in line 3 is withdrawn.

Cancellation of said claim has rendered the rejection moot.

Claim Rejections Maintained and New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5, 27-28 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claim to recite "wherein on administration to swine said composition induces the production of antibodies to 21 kD, 31kD, 43-44kD, 60kD and 71kD antigens found on said *L. intracellularis* by Western blot analysis". This phrase does not appear in the specification or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. No demonstration is set forth in the specification that administration of the claimed composition to swine would result in the production of antibodies to all of the recited antigens. Therefore this limitation is new matter.

Claims 3-5, 27-28 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the cell strain represented by the ATCC accession number 55370 is required in order to practice the invention. Specifically, it is noted that claim 27 recites deposited material and that claims 3-5, 28 and 31 are depend from the claim reciting deposited material. The deposit of biological organisms is considered by the Examiner to be necessary for the enablement of the current invention (see 37 CFR 1.808(a)). The examiner acknowledges the deposit of organisms under the ATCC accession number 55370 in partial compliance with this requirement. However, said deposits are not in full compliance with 37 CFR 1.803-1.809.

If the deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit, or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent; and

3) the deposits will be maintained for a term of at least thirty (30) years from the date of the deposit or for the enforceable life of the patent or for a period of at least five (5) years after the most recent request for the furnishing of a sample of the deposited material, whichever is longest; and

4) a viability statement in accordance with the provisions of 37 CFR 1.807; and

5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 – 1.809 for additional explanation of these requirements.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 3-5 and 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Knittel et al. (WO 96/369629 – IDS-14) in view of Joens et al (U.S. Patent 5,610,059 - IDS-4) is maintained for reasons of record.

Applicant argues:

1. There is no disclosure by Joens et al. regarding the actual production or use of a vaccine.
2. Joens et al. is limited to the isolation, characterization and production of the strain deposited as ATCC No. 55370.
3. Nothing more than conventional methods for producing a vaccine are discussed in the hypothetical.
4. In view of the lack of predictability in the vaccine art, the disclosure of Joens et al. provides nothing more than a suggestion to make a vaccine by conventional methods which fails to provide the reasonable expectation of success necessary to support a conclusion of obviousness.
5. Joen's hypothetical discussion of a vaccine may have provided motivation, but it is not an enabling disclosure and hence cannot be relied on for nothing beyond the specific deposited strain.

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6. Knittel et al. disclose *L. intracellularis* vaccines using both attenuated and killed *L. intracellularis*.
7. The success of one strain of as a vaccine does not predict success with any other.
8. With the present amendments, the instant invention includes the limitations whereby the *L. intracellularis* antigen component consists essentially of the strain deposited as ATCC No. 55370 that on administration to swine induces the production of antibodies to specific antigens that were identified by Western blot. The claims are now limited to vaccine compositions in which the *L. intracellularis* must be the specific tissue culture produced, whole cell *L. intracellularis* deposited as ATCC deposit No. 55370.
9. Until the present invention the protective immunity demonstrated by the claimed vaccine composition could not be reasonably be assured.

Applicant's arguments have been fully considered and deemed non-responsive.

With regard to Points 1-3, Applicant's assertions are contrary to what is disclosed in the specification. On page 7, lines 6-7, the specification states that "U.S. Patent 5,610,059 (Joens et al.) describes general methods for preparing inactivated and modified or attenuated vaccine". Said vaccines utilized the materials deposited as ATCC deposit No. 55370.

With regard to Points 4-5, 7 and 9, as evidenced by Applicant's own admission (see above), U.S. Patent 5,610,059 provides not only motivation but provides the skilled artisan with a reasonable expectation of success.

With regard to Point 8, since the vaccine compositions resulting from the combination of the cited references and the instant invention are the same, one would necessarily expect them to induce the same antibody responses when administered to a swine.

As outlined previously, Knittel et al. disclose vaccine compositions comprising inactivated whole cell *L. intracellularis* or lysates thereof and an adjuvant (see page 17-18 and Example 6) [Applicant's Point 6] and the use of said vaccines in swine. Knittel further disclose that said bacteria can be inactivated by the addition of formalin (see page 17, lines 30-33) and that the adjuvant used could be aluminum hydroxide (see page 18, lines 1-4). Knittel et al. differ from the instant invention in that they don't explicitly disclose the use of the organism with the ATCC deposit No. 55370. Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* is further disclosed to be inoculated into porcines in order to check its pathogenicity (see examples 1 and 2). Moreover, the isolated *L. intracellularis* disclosed by Joens et al. was deposited with ATCC with the deposit number 55370 (see column 8, lines 14-21 and claim 1). Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation (see column 4, lines 6-16) said bacterin could be administered to porcines to "permit the pigs to mount an effective immune response against the agent (PPE)". Therefore it would have been obvious to one of skill in the art to use the antigen disclosed by Joens et al. (ATCC deposit No. 55730) in the vaccine compositions of Knittel et al. Moreover, it would have been equally obvious to use the resulting vaccine compositions to protect swine from diseases caused by *L. intracellularis* infection. Contrary to Applicant's assertion, the disclosure by Joens et al. that said bacterin (immunogen) could be administered to pigs to "permit the pigs to mount an

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effective immune response against the agent (PPE) would provide one of skill in the art not only of a reasonable expectation of success but a motivation to use the disclosed antigen (ATCC, No. 55730) as a vaccine. Moreover, it is not necessary for the skilled artisan to be assured of success, he merely has to have a reasonable expectation of success. Therefore, for the reasons set forth above, the combination of the disclosures by Knittel et al. and Joens et al. renders all the rejected claims obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robert A. Zeman
September 27, 2004